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09/461,308	12/15/1999	TAIZO AKIMOTO	Q56519	3646

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

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21

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/461,308

Applicant(s)

AKIMOTO, TAIZO

Examiner

Frank W Lu

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
  2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
  3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)                      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on September 16, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/461,308 is acceptable and a CPA has been established. The claims pending in this application are claims 25-36. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn. An action on the CPA follows.

### ***Claim Objections***

2. Claim 25 is objected to because of the following informalities: the phrase "for each of said plurality of predetermined positions" should be deleted since this phrase does not make sense in view of description of a first detection means in lines 3-6.

Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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4. Claims 25 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Kubista *et al.*, (Sweden Patent 9703251-0, published on April 19, 1999, for English translation, see WO 99/13105).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Kubista *et al.*, teach nucleic acid array and hybridization. Figures 2 and 3B showed that an array immobilized plurality of different oligonucleotides comprising a sequence recognizing part (SID) and a reporting group (RG) (see page 3). The reporting group could be a coloring agent such as fluorescent dye as recited in claim 29 (see page 1, second paragraph and Figure 4). The hybridization was performed using a fluorescence labeled nucleic acid probe. The fluorescences on immobilized plurality of different oligonucleotides ( a first detection means) and the nucleic acid probe ( a second detection means) could be different and could served as fluorescence energy transfer pairs. The signals before and after hybridization were monitored. The difference in signal strength at these determinations was considered as a hybridization signal wherein the detected level of a second labeling signal was corrected for the detected level of a first labeling signal as recited in claim 25 (see pages 2, first and second paragraphs, Figure 3B and Example). Kubista *et al.*, was considered to teach an analyzing means for measuring a quantity of said organism-originated substance bound to said specific binding substance since they showed that the signals before and after hybridization were monitored and the difference in signal strength at these determinations was considered as a hybridization signal (see above).

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Therefore, Kubista *et al.*, teach all limitations recited in claims 25 and 29. .

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kubista *et al.*, (1999) as applied to claims 25 and 29 above.

The teaching of Kubista *et al.*, have been summarized previously, *supra*. Note that labeled nucleic acid probe could be either fluorescent or radioactive (see page 2, first paragraph).

Kubista *et al.*, did not disclose to a first detection means for detecting a level of a first labeling signal emitted by a first labeling substance wherein said first labeling substance is a radioactive isotope as recited in claim 33.

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However, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a first detection means for detecting a level of a first labeling signal emitted by a first labeling substance wherein said first labeling substance was a radioactive isotope. One having ordinary skill in the art would have been motivated to modify the apparatus of Kubista *et al.*, because the simple substitution of one kind of label material for first labeling substance (i.e., labeled with fluorescence) from another kind of label material for first labeling substance (i.e., labeled with radioactive) during the process of making the first detection means would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

7. Claims 26, 30, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubista *et al.*, (1999) as applied to claims 25 and 29 above, and further in view of Brown *et al.*, (US Patent 5, 807, 522, filed on June 7, 1995).

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The teaching of Kubista *et al.*, have been summarized previously, *supra*.

Kubista *et al.*, did not disclose a first detection means for detecting a level of a first labeling signal emitted by a first labeling substance wherein said first labeling substance labels a plurality of known different specific binding substances and said binding substances are cDNAs as recited in claim 26.

Brown *et al.*, teach fabricating microarrays coated with a layer of poly-L-lysine (Sigma) with immobilized biological samples. As described in example 2, the cDNA clones were spotted on poly-L-lysine coated microscope slides. Total poly-A mRNA from wild type *Arabidopsis* was isolated using standard methods (Maniatis, *et al.*, 1989) and reverse transcribed into total cDNA, using a fluorescein nucleotide analog to label the cDNA product (green fluorescence). Two micrograms of the cDNA products from each type of plant were pooled together and hybridized to the cDNA clone array in a 10 microliter hybridization reaction (fifth and sixth paragraphs of column 17).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a first detection means for detecting a level of a first labeling signal emitted by a first labeling substance wherein said first labeling substance labeled a plurality of known different specific binding substances and said binding substances were a cDNA labeled with either fluorescence or radioactive in view of prior art of Kubista *et al.*, and Brown *et al.*. One having ordinary skill in the art would have been motivated to modify the apparatus of Kubista *et al.*, because labeling the cDNAs with a fluorescein nucleotide analog was known in the art at the time the invention was

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made (see above, Brown *et al.*), the simple substitution of one kind of immobilized nucleic acids (i.e., oligonucleotides) with another kind of immobilized nucleic acids (i.e., cDNAs), and the simple substitution of one kind of label reagent (i.e., fluorescence) from another kind of label reagent (i.e., radioactive) during the process of making the first detection means, would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

### ***Conclusion***

8. Claims 27, 28, 31, 32, 35, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official



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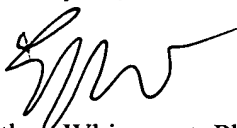
Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu  
January 24, 2003



Ethan Whisenant, Ph. D.  
Primary Examiner (FSA)